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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,412	12/17/2003	Michelle D. Hines	SC65U-US	8911

60723 7590 07/18/2007

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
07/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,412	HINES ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 10-57* is/are pending in the application.

4a) Of the above claim(s) *28-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 10-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 6/6/2007 have been fully considered. Applicant's amendments to the claims by limiting the compound in claim 1 to 2-amino-4,5-dimethylthiazole are sufficient to overcome the 35 U.S.C. 112, first paragraph rejection and the rejection is hereby withdrawn.

Applicant's arguments over the 35 U.S.C. 102(b) rejection over U.S. Pg-Pub 2002/0022622 are persuasive and the rejection is withdrawn. Applicant's argue that Wagle teaches an infinite number of species with which the Examiner agrees that Wagle does teach an infinite number of species as drawn to the compound of formula I (in claim 1) and does not anticipate the 2-amino-4,5-dimethylthiazole of the instant application.

However, applicants further argue that the Wagle reference does not disclose 2-amino-4,5-dimethylthiazole. This argument is not found persuasive because Wagle teaches compositions that meet the limitation of a thiazole, as well as the instant 2-amino-4,5-dimethylthiazole. In particular, Formula I in paragraph 0004 meets the 2-amino-4,5-dimethylthiazole when J is sulfur, R is amino and R^a and R^b are both methyl (see paragraphs 0016-0021). Applicants further argue that Wagle does not exemplify any 2-aminothiazole derivatives where both R^a and R^b constitute alkyl groups and that Wagle may lead one skilled in the art away from the 2-amino-4,5-dimethylthiazole species. This argument is also not persuasive because Wagle teaches that R^a and R^b may be methyl and does not say that either R^a or R^b may be methyl. In addition, the closest two compounds that are specifically stated are 2-amino-5-methylthiazole and 2-

amino-4-methylthiazole (paragraphs 0140-0141), and it is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results (see rejection below for further explanation). Applicant's arguments that the Wagle reference is not enabling for the present 2-amino-4,5-dimethylthiazole is not persuasive because, as discussed above, the 2-amino-4-methylthiazole and 2-amino-5-methylthiazole taught by Wagle render the present compound obvious.

Applicant's amendments to the claims necessitated the following new grounds of rejection. In addition, claims 1 and 10-27 are being examined as they read on a cosmetic or pharmaceutical composition, the intended use of the composition is not given any patentable weight.

Claim Rejections – 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 10-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Wagle et al. (US Pg-Pub 2002/0022622) in view of Gould (Int J Pharmaceutics, 33 (1986) 201-217).

Wagle et al. teaches pharmaceutical compositions that meet the limitation of the 2-amino-4,5-dimethylthiazole of claim 1. In particular, Formula I in paragraph 0004

corresponds to 2-amino-4,5-dimethylthiazole when J is sulfur, R^a and R^b are alkyl and R is amino (meeting the limitations of claims 1, 15-18 and 23; see also claim 1). Though this particular compound is not stated within the reference, two closely related compounds are specifically stated which are 2-amino-5-methylthiazole and 2-amino-4-methylthiazole. It is well established that the substitution of methyl for hydrogen on a known compound is not a patentable modification absent unexpected or unobvious results. In re Lincoln, 126 U.S.P.Q. 477, 53 U.S.P.Q. 40 (C.C.P.A. 1942). Wagle further teaches that the compositions of the invention typically include a vehicle (further meeting the limitation of claim 1; paragraph 0278). The compositions are further formulated with pharmaceutically acceptable salts (meeting the limitation of claims 13 and 21; paragraph 0125, 0248, and claim 1).

Wagle et al. do not specifically teach the hydrochloride salt or the weight percentages of the composition.

Gould et al. teaches that salt formation provides a means of altering the physicochemical and resultant biological characteristics of a drug without modifying its chemical structure and teaches that hydrochloride is an FDA-approved commercially marketed salt (Table 1).

Furthermore, it is obvious to vary and/or optimize the amount of 2-amino-4,5-dimethylthiazole provided in the composition, according to the guidance provided by Wagle et al., to provide a composition having the desired properties such as the desired percentages that will effectively treat a disease or a condition. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to

discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would be obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Wagle et al. with Gould et al. because Gould et al. teach that hydrochloride is an FDA-approved commercially marketed salt. One would be motivated to combine the references and add the hydrochloride salt to 2-amino-4,5-dimethylthiazole in an effort to stabilize the compound.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER